

## **REMARKS**

In response to the Final Action dated July 28, 2009, and subsequent to the filing of a Response under 37 C.F.R. §1.116 on October 21, 2009, Applicants respectfully submit the foregoing supplemental amendments to the specification and the claims.

Specifically, the specification has been amended to include the deposit information for the hybridomas that secrete monoclonal antibodies 16H2 and 20F8. The deposits were made on May 20, 2003 with ECACC, as evidenced by the attached ECACC documents stating that the deposits were accepted by ECACC as patent deposits in accordance with the Budapest Treaty of 1977.

Applicants further submit that all restrictions on availability of these hybridomas to the public will be irrevocably removed upon the granting of the patent based upon the captioned application and the hybridomas will remain permanently available for a term of at least 5 years after the most recent request for the furnishing of a sample, and in any case, for a period of at least 30 years after the date of deposit or for the enforceable life of the U.S. patent whichever is longer. In the event that the hybridomas become non-viable or are inadvertently destroyed, such will be replaced with viable hybridomas of the same taxonomic description.

Further, claims 18 and 23 have been amended to insert the accession numbers of the deposited hybridomas. Additionally, claim 18 has been amended to delete the language "mutant or variant thereof".

No new matter is introduced by the foregoing amendments.

In view of the foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited. Should the Examiner believe that a telephone discussion will be helpful in resolving any outstanding issue, the Examiner is requested to contact the undersigned at the number indicated below.

Respectfully submitted,

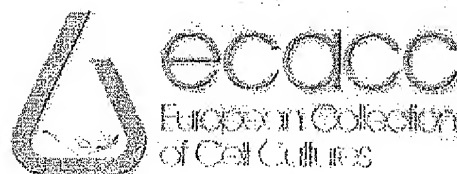
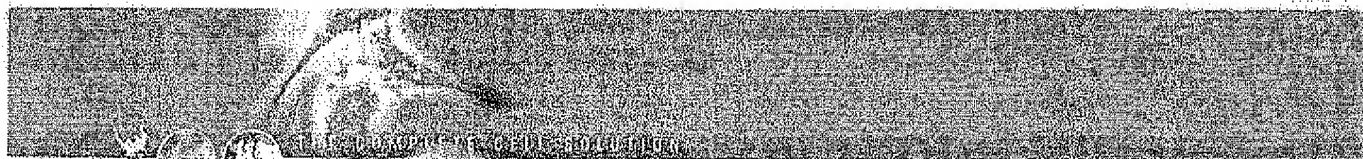
A handwritten signature in black ink, appearing to be 'XZ' followed by a stylized flourish.

Xiaochun Zhu

Registration No. 56,311

Scully, Scott, Murphy & Presser, P. C.  
400 Garden City Plaza, Suite 300  
Garden City, New York 11530  
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XZ:ab/dk

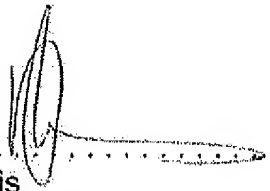
Enc.: ECACC deposit documents.



# Centre for Applied Microbiology and Research and European Collection of Cell Cultures

This document certifies that  
Hybridoma LM04 16H2.C1.B8  
Deposit Reference 03052001

has been accepted as a patent deposit, in accordance with  
The Budapest Treaty of 1977,  
with the European Collection of Cell Cultures on  
20 May 2003

  
.....  
Dr D H Lewis  
General Manager  
ECACC



European Collection of Cell Cultures, CAMR, Salisbury, Wiltshire SP4 0JG UK.

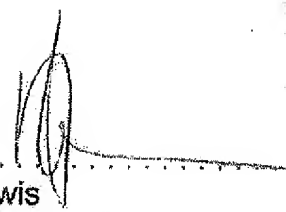
Tel: 44 (0) 1980 612512 Fax: 44 (0) 1980 611315 Email: [ecacc@camr.org.uk](mailto:ecacc@camr.org.uk) Web Site: [ecacc.org.uk](http://ecacc.org.uk)



# Centre for Applied Microbiology and Research and European Collection of Cell Cultures

This document certifies that  
Hybridoma LM04 20F8.B2.C8  
Deposit Reference 03052002

has been accepted as a patent deposit, in accordance with  
The Budapest Treaty of 1977,  
with the European Collection of Cell Cultures on  
20 May 2003.



Dr D H Lewis  
General Manager  
ECACC



European Collection of Cell Cultures; CAMR, Salisbury, Wiltshire SP4 0JG UK.

Tel: 44 (0) 1980 612512 Fax: 44 (0) 1980 611315 Email: [ecacc@camr.org.uk](mailto:ecacc@camr.org.uk) Web Site: [ecacc.org.uk](http://ecacc.org.uk)

BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSES OF PATENT PROCEDURE.

TO  
DR L WILSON  
WALTER & ELISA HALL INSTITUTE OF ME

INTERNATIONAL FORM

POST OFFICE  
ROYAL MELBOURNE HOSPITAL  
PARKVILLE  
VIC 3050  
AUSTRALIA

NAME AND ADDRESS  
OF DEPOSITOR

I. IDENTIFICATION OF THE MICROORGANISM	
Identification reference given by the DEPOSITOR: LM04 20F8.B2.C8	Accession number given by the INTERNATIONAL DEPOSITORY AUTHORITY: 03052002
II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION	
<p>The microorganism identified under I above was accompanied by:</p> <p><input checked="" type="checkbox"/> A scientific description</p> <p><input type="checkbox"/> A proposed taxonomic designation</p> <p>(Mark with a cross where applicable)</p>	
III. RECEIPT AND ACCEPTANCE	
<p>This International Depository Authority accepts the microorganism identified under I above, which was received by it on 20 May 2003 (date of the original deposit)</p>	
IV. RECEIPT OF REQUEST FOR CONVERSION	
<p>The microorganism identified under I above was received by this International Depository Authority on (date of the original deposit) and</p> <p>A request to convert the original deposit to a deposit under the Budapest Treaty was received by it on (date of receipt of request for conversion)</p>	
IV. INTERNATIONAL DEPOSITORY AUTHORITY	
<p>Name: Dr D H Lewis</p> <p>Address: ECACC CMR Porton Down Salisbury SP4 0JG</p>	<p>Signature(s) of person(s) having the power to represent the International Depository Authority or of Authorized official(s):</p> <p>Date: 16/3/04</p>

1 Where Rule 6.4(d) applies, such date is the date on which the status of international depository authority was acquired

BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSES OF PATENT PROCEDURE

## INTERNATIONAL FORM

TO  
DR L WILSON  
WALTER & ELISA HALL INSTITUTE OF ME

POST OFFICE  
ROYAL MELBOURNE HOSPITAL  
PARKVILLE  
VIC 3050  
AUSTRALIA

VIABILITY STATEMENT  
Issued pursuant to Rule 10.2 by the  
INTERNATIONAL DEPOSITARY AUTHORITY  
identified on the following page

NAME AND ADDRESS OF THE PARTY  
TO WHOM THE VIABILITY OF STATEMENT  
IS ISSUED

I. DEPOSITOR	II. IDENTIFICATION OF THE MICROORGANISM
<p>Name: DR L WILSON WALTER &amp; ELISA HALL INSTITUTE OF ME</p> <p>Address: POST OFFICE ROYAL MELBOURNE HOSPITAL PARKVILLE VIC 3050 AUSTRALIA</p>	<p>Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY:  03052002</p> <p>Date of the deposit or of the transfer:  20 May 2003</p>
II. VIABILITY STATEMENT	
<p>The viability of the microorganism identified under II above was tested on 20 May 2003. On that date, the said microorganism was</p> <p><input checked="" type="checkbox"/> viable</p> <p><input type="checkbox"/> no longer viable</p>	

1. Indicate the date of the original deposit or, where a new deposit or a transfer has been made, the most relevant date (date of the new deposit or date of the transfer).
2. In the cases referred to in Rule 10.2 (a) (ii) and (iii), refer to the most recent viability test.
3. Mark with a cross the applicable box.

Form BP/4 (first page)

IV. CONDITIONS UNDER WHICH THE VIABILITY TEST HAS BEEN PERFORMED <sup>4</sup>	
II. INTERNATIONAL DEPOSITARY AUTHORITY	
Name: Dr D H Lewis ECACC CAMR Address: Porton Down Salisbury Wiltshire SP4 6JG.	Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s): Date: 16/3/04

<sup>4</sup> Fill in if the information has been requested and if the results of the test were negative.

Form BP/9 (second and last page)

## Certificate of Analysis

Product Description: LM04 16H2.CL.B8  
Lot Number: 03/K/011

Test Description: Cell Count, Viability and confluency of cells on resuscitation from frozen.

Acceptance Criterion/Specification: were judged acceptable if they meet two of the following criteria:

- >70% viable cells
- $>2 \times 10^6$  viable cells/ml
- confluent in 2 days

Date: 09/01/04

Result:  
Viable Cell Count:  $1.78 \times 10^7$  cells/ml  
Percentage Viability: 41%  
Confluent in: Good Growth in 2 days

Test Description: The Detection of Mycoplasma by Isolation on Mycoplasma Pig Serum Agar and in Mycoplasma Horse Serum Broth.  
SOP QC/MYCO/01

Acceptance Criterion/Specification: All positive controls (*M. pneumoniae* & *M. orale*) must show evidence of mycoplasma by typical colony formation on agar plates. Broths are subcultured onto Mycoplasma Pig Serum Agar where evidence of mycoplasma by typical colony formation is evaluated. All negative control agar plates must show no evidence of microbial growth.

The criteria for a positive test result is evidence of mycoplasma by typical colony formation on agar. A negative result will show no such evidence.

Test Number: 28717

Date: 09/02/04

Result:  
Positive Control: Positive  
Negative Control: Negative  
Test Result: Negative  
Overall Result: PASS

Authorised by: *Ann Wilson* A. Wilson, ECACC, Head of Quality 18/2/04 Date



## Certificate of Analysis

Product Description LM04 16H2.CL.B8  
Lot Number 03/K/011

Test Description: Detection of Mycoplasma using a Vero indicator cell line and Hoechst 33258 fluorescent detection system.  
SOP QC/MYCO/07

Acceptance Criterion/Specification: The Vero cells in the negative control are clearly seen as fluorescing nuclei with no cytoplasmic fluorescence. Positive control (*M. orale*) must show evidence of mycoplasma as fluorescing nuclei plus extra nuclear fluorescence of mycoplasma DNA. Positive test results appear as extra nuclear fluorescence of mycoplasma DNA. Negative results show no cytoplasmic fluorescence.

Test Number: 28717  
Date: 19/01/04  
Result:  
Positive Control: Positive  
Negative Control: Negative  
Test Result: Negative  
Overall Result: PASS

Test Description: Sterility Testing of Cell Banks (SOP ECACC/048)

Acceptance Criterion/Specification: All positive controls (*Bacillus subtilis* and *Candida albicans*) show evidence of microbial growth (turbidity) and the negative controls show no evidence of microbial growth (clear).  
The criteria for a positive test is turbidity in any of the test broths. All broths should be clear for negative test result.

Test Number: 28717  
Date: 12/12/03  
Result:  
Positive Control: Positive  
Negative Control: Negative  
Test Result: Negative  
Overall Result: PASS

Test Description: Monoclonal Antibody Isotyping.  
SOP ECACC/019

Acceptance Criterion/Specification: The light chain and isotype detected match those expected. A band appears in the positive control region.

Test Number: 28717  
Date: 22/01/04  
Result:  
Positive Control: Positive  
Expected Result: Unknown  
Test Result: IgG2a

Authorised by                      ECACC, Head of Quality, 18/2/04 Date

## Certificate of Analysis

Product Description      LM04 20F8.B2.C8  
Lot Number                03/K/012

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Test Description:      Cell Count, Viability and confluency of cells on resuscitation from frozen.

Acceptance Criterion/Specification: were judged acceptable if they meet two of the following criteria:

- >70% viable cells
- >2 x 10<sup>6</sup> viable cells/ml
- confluent in 2 days

Date:                    09/01/04

Result:                Viable Cell Count:      1.02 x 10<sup>7</sup> cells/ml  
                         Percentage Viability:    57%  
                         Confluent in:            Good Growth in 2 days

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Test Description:      The Detection of Mycoplasma by Isolation on Mycoplasma Pig Serum Agar and in Mycoplasma Horse Serum Broth.  
                                 SOP QC/MYCO/01

Acceptance Criterion/Specification:      All positive controls (*M. pneumoniae* & *M. orale*) must show evidence of mycoplasma by typical colony formation on agar plates. Broths are subcultured onto Mycoplasma Pig Serum Agar where evidence of mycoplasma by typical colony formation is evaluated. All negative control agar plates must show no evidence of microbial growth.  
The criteria for a positive test result is evidence of mycoplasma by typical colony formation on agar. A negative result will show no such evidence.

Test Number:      28716

Date:                    09/02/04

Result:                Positive Control:      Positive  
                         Negative Control:      Negative  
                         Test Result:            Negative  
                         Overall Result:        PASS

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Authorised by: John A. Kelly ECACC, Head of Quality, 18/1/04 Date

## Certificate of Analysis

Product Description      LM04/20F8.B2.C8  
Lot Number                03/K/012

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Test Description:      Detection of Mycoplasma using a Vero indicator cell line and Hoechst 33258 fluorescent detection system.  
SOP QC/MYCO/07

Acceptance Criterion/Specification: The Vero cells in the negative control are clearly seen as fluorescing nuclei with no cytoplasmic fluorescence. Positive control (*M. orale*) must show evidence of mycoplasma as fluorescing nuclei plus extra nuclear fluorescence of mycoplasma DNA. Positive test results appear as extra nuclear fluorescence of mycoplasma DNA. Negative results show no cytoplasmic fluorescence.

Test Number:    28716  
Date:            19/01/04  
Result:

Positive Control:	Positive
Negative Control:	Negative
Test Result:	Negative
Overall Result:	PASS

---

Test Description:      Sterility Testing of Cell Banks (SOP ECACC/048)

Acceptance Criterion/Specification:      All positive controls (*Bacillus subtilis* and *Candida albicans*) show evidence of microbial growth (turbidity) and the negative controls show no evidence of microbial growth (clear).  
The criteria for a positive test is turbidity in any of the test broths. All broths should be clear for negative test result.

Test Number:    28716  
Date:            12/12/03  
Result:

Positive Control:	Positive
Negative Control:	Negative
Test Result:	Negative
Overall Result:	PASS

---

Test Description:      Monoclonal Antibody Isotyping.  
SOP ECACC/019

Acceptance Criterion/Specification:      The light chain and isotype detected match those expected. A band appears in the positive control region.

Test Number:    28716  
Date:            22/01/04  
Result:

Positive Control:	Positive
Expected Result:	Unknown
Test Result:	IgG2a

Authorised by Chen Sheng Alloy ECACC, Head of Quality 15/2/04 Date